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Original Research Article

Preliminary outcome data of a Sino-European-Prevention-Program (SEPP) in individuals with perceived stress

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Keywords

- Lifestyle program
- Stress reduction program
- Traditional Chinese Medicine
- Outcome study
- Yang Sheng
- IHM

Abstract

Background: The health resort Bad Kötzing, in Germany, has developed a lifestyle-program called the “Sino-European-Prevention-Program” (SEPP) a combination of a Western lifestyle program, named “Individual Health Management” (IHM), supplemented by various elements of Traditional Chinese Medicine (TCM), called YangSheng (life care).

Objective: This pilot study aimed to evaluate the outcome of SEPP in individuals with perceived stress.

Methods: To recruit suitable participants, a screening concept with a web-based health portal along inclusion and exclusion criterions was realized. The study followed an observational design without control group. Participants passed through a 6-month lasting lifestyle program with 3 introduction days, 10 after-works with 2-hours sessions and 3 refresher days. Outcomes measures were formed by Tedium score, ISR, PSQ as primary indicators. Secondary parameters included Life Satisfaction (FLZ), neuro-vegetative questionnaire, 5-Wellbeing Index and general health indicators.

Results: All outcome-parameters consistently showed relevant improvements during the intervention. Gained experiences supported logistic aspects of a prospective controlled clinical trial to explore the effectiveness of SEPP.

Conclusion: SEPP is a feasible concept for a web-based lifestyle program in a specialized SPA-region with suspected effectiveness in people with perceived stress and should be evaluated in a randomized controlled design next.

Abbreviations: SEPP: Sino-European-Prevention-Program; IHM: Individual Health Management; TCM: Traditional Chinese Medicine; ISR: ICD-10-Symptom-Rating; PSQ: Perceived Stress Questionnaire

INTRODUCTION

Since 2008, the health resort area of Bad Kötzing, in southeast Germany, grew into a center of preventive medicine.

Due to its unique feature, with its having the first German hospital for Traditional Chinese Medicine (TCM), content and marketing emphases are to be placed on the field of Chinese medicine [1]. To achieve this, a new course of treatment needs to be developed and evaluated. The Bad Kötzing TCM hospital has been accompanied by the Klinikum rechts der Isar Technical University Munich (TUM) Competence Centre for Complementary Medicine and Naturopathy (CoCoNat) for many years now. Both facilities have developed an extensive preventive medicine lifestyle program named “Individual Health Management” IHM [2]. The concept of IHM has been rudimentarily established in

the first German clinic for Traditional Chinese Medicine (TCM), Kötzing, as a “western” supplementary for Traditional Chinese Medicine. With this as part of the plan, basic medical experience, technical prerequisites and training resources were on location. Public funds provided by the Bavarian Federal Health Office were made available for the development of a so called Sino European Prevention Program (SEPP). SEPP complies with the wishes of many of those who would like to activate their own resources and the health supporting potential for self-healing by making use of both conventional and TCM/YangSheng methods [3].

The use of organismic and psycho-social, as well as cognitive personal contributions, to remain healthy are a core issue of complementary medicine. However, to date, these have not been adequately put to use. The strengthening of salutogenic resources and protective factors for health maintenance have a pro-active

effect and do not wait – viewed systematically – until sickness and their consequences have received medical treatment. There is a global trend indicating stronger active involvement of persons for the maintenance and restoring of health. Therefore, various individuals would especially prefer a combination of lifestyle recommendations and measures from complementary and conventional medicine [4].

Stress load was selected as the first indication to evaluate SEPP. Maladaptation on chronic stress-conditions and psychological distress may cause or foster burnout, anxiety, depression but also overweight, high blood-pressure, and diabetes mellitus [5]. SEPP should enable people to learn a sufficient stress-management for a better regulation of their own emotions which should result in a reduced perceived stress level. If necessary or if desired, it will be possible to organize a pursuing examination and treatment carried out by TCM doctors or specialist doctors within the scope of a spatial and time-related full range offer. To accomplish this, Bad Kötzting – with the help of Federal, European and private investments and subsidies – has created a new prevention centre on location, named Sinocur®, which is able to realize these prerequisites.

MATERIALS AND METHODS

General Concept of SEPP

Individual Health Management (IHM) is a lifestyle concept based on validated scientific knowledge of successful changes in lifestyle, and has been designed as a “blended learning” program for both healthy persons and persons suffering from sickness [6]. “Blended learning” means the mixing and linking of modern E-Health-Technologies with traditional personally attended lessons or counselling. With this, an attempt is made to cope with the problems of the lack of sustainability and pedagogical mediation by directing towards coaching. The web based health portal under the name VITERIO® (Virtual Tool for Education, Reporting and Outcomes) represents the technical background of the IHM lifestyle program. The IHM as a lifestyle program comprises the systematic observation of risk and protective factors, symptom and result monitoring. It orientates itself on both salutogenic models and the theory of a health-illness-continuum, with the goal of during both health and illness, strengthening individuals in their self-determination, self-competence and own responsibility [7,8]. Background theories are among others, the training of emotional competences according to Berking [9] and the rational-emotive behavioural therapy according to Ellis [10]. The central element of IHM is self-management, which enables the individual to care for and optimise his or her own so called physiological basis functions (exercising, nutrition, vegetative balance, resistance, thermal balance, sleep, rhythm), as well as psychosocial and cognitive basis competences (self-competence, social competence) during daily life. This is aimed at sustainably increasing, preserving or restoring the personal quality and satisfaction of life through a healthy lifestyle (train to target) and is achieved pedagogically by means of a long health program, lasting for a period of at least 12 months, which links modern e-Health-Technologies to personal support in the forms of health coaching, medical counselling and possibly naturopathic treatment (treat-

to-target). With the assistance of an electronic algorithm, various risk-groups (test – healthy, slight and moderate overweight, pre-diabetes, pre-hypertension, pre-burnout, diabetes, high blood pressure, burnout, tobacco addiction, and obesity) are formed, and individual lifestyle recommendations as training packages are modified and prepared. The meta-goals are an improvement in life satisfaction, with an increase in one’s physical and mentally healthy years of life.

Traditional Chinese Medicine (TCM) and Chinese life care (YangSheng) are more than 2500-years old medical systems [3]. The therapies used in these systems are medicines, acupuncture, thermal application (moxibustion), cupping massage (Guasha), massages (Tuina), respiratory therapy and the therapeutic exercises Qigong and Chinese dietetics [3]. YangSheng is made up of the words “Yang” (to take care of and come close to) and Sheng (life, birth and vitality). Linking both terms means to take care of life or to support health and well-being by taking care of the body, mind and soul and to live in harmony with natural rhythms and universal principles.

Elements of YangSheng are dietetics, exercise (Qigong), massage (also acupressure) and general codes of behaviour such as sleep-hygiene. The individual’s constitutional type is of importance during the process of deciding which exact lifestyle measures are recommendable. To enable the determination of the constitutional type, a modified questionnaire for TCM constitution determination by Professor Wang Qi recommended as a standard method by the China Association of Chinese Medicine is put to use [5,11-14]. The standardized questionnaire differentiates between nine diverse constitutional types: healthy balance, Qi-deficiency, Yang-deficiency, Yin-deficiency, phlegm-wetness, wetness-heat, blood-stasis, Qi depression, special diathesis [13]. The individual constitutional types are largely, in a western sense, neuro-vegetative functional tendencies. Qi-deficiency can, for example, be described as a vegetative functional tendency of “lack of cooling and moistening”. The symptoms for this can be described as having a tendency to “hot palms of the hand and soles of the feet”, a “hot feeling in the face or whole body” with “dry skin (lips)”, constipation, “dry eyes” and “sweating during only slight movement”. In contrast, a “Yang-deficiency” shows a neuro-vegetative functional tendency with typical symptoms being “lack of warming up” with cold hands and feet, “a cold feeling in the stomach, back, knees” as well as a “tendency to feel the cold”, “cold intolerance with air conditioning or fans”, “intolerance with cold meals” and “diarrhea, subsequent to eating cold meals or raw fruit and vegetables”.

Implementation of SEPP

The concept of SEPP had to be adapted for a pilot group of roughly 12 persons suffering from perceived stress. This program encompasses access to a web-based health portal (www.viterio.de) and three full-day called ‘introduction days’ plus ten, not less than 2-hour training sessions during the first 3 months. All training sessions were to be performed in the local study center. After 12 weeks, for the first and last remaining three months, further one refresher training should be conducted (for details see Figure 1).

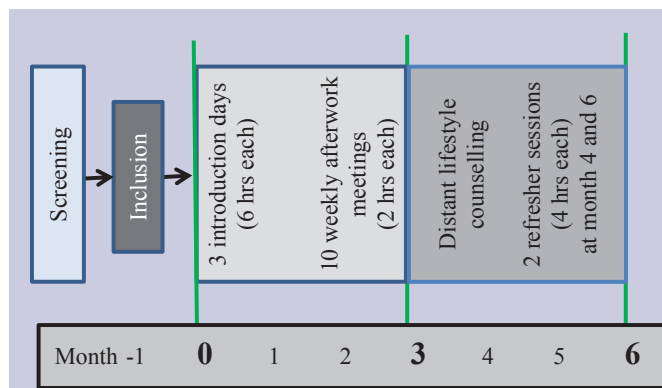


Figure 1: Flow chart of the SEPP intervention and study design

The TCM constitution questionnaire has been translated into German and has been integrated in the IHM web based portal as TCM screening. During the second stage, YangSheng lifestyle recommendations regarding nutrition, exercise and acupressure were developed in CoCoNat for the individual constitutional types and modified and integrated in the respective western risk-group oriented IHM lifestyle recommendations.

At the beginning of the introductory phase, participants receive a so called “starter kit”, which includes a pedometer, a measuring tape and a “state of mind” scale (possibly also a blood pressure meter) to enable them carry out the self-observation exercises. The ability of personal self-perception is a very important component part of SEPP and a condition for achieving successful changes in life. Within the scope of result and behavior documentation of a typical routine week, the individual has to learn to record his or her personal exercise and nutritional behavior, as well as his or her individual body state (weight, blood pressure). During a further observation week, participants learn to get to know their life better by recording various tasks in everyday life and occupation, and by documenting the amount of time spent with each task and with which personal feeling and mood they are linked to. This account makes it simpler for the participant to recognize where he or she has the desire to make amendments to his or her personal lifestyle.

The self-observation week should be repeated every three months to show the attitude and behavior in one’s own lifestyle.

A special emphasis during the adaption of the western IHM-Lifestyle-Recommendation program is made up of the nutritional and exercise packages. The nutritional recommendations target especially the strengthening of various important TCM functional areas, such as “kidneys, spleen and liver”. The nutrients recommended by the Chinese side of the program have been adapted to the nutrient conditions in Germany with medical-functional equivalent western nutrients being given preference. With this, replacements were found for Chinese nutrients not appearing to be suitable, due to their structure, availability and/or acceptance. The same also applies to TCM medicines, respectively for natural substances and medicinal plants put to use.

Exercise recommendations were expanded with the use of “3-1-2 Meridian Exercise Therapy”. This special sequence

of exercises – specified by Professor Zhu Zong-Xiang from the Institute for Biophysics, Chinese Academy of Science and Acupuncture-Meridian Research Centre in Beijing - is already practiced worldwide [15].

3-1-2 Meridian Exercise Therapy consists of three elements:

“3” – Putting pressure on three of the most important acupuncture points from 14 of the human body meridians (acupressure).

“1” – A deep stomach respiratory exercise is carried out.

“2” – Body exercises are carried out for a short time whilst standing (both feet on the ground) (for instance – knee bends).

The stress management package includes multimodal stress management, which at first, with the assistance of a time-mood-analysis, should make possible the identification of personal stress factors during the daily routine, and, with this, in individual cases have direct influence on stress triggers. The area regenerative-palliative stress management is directly applied – regarding the stress reaction level – to stress reactions. Chiefly, with vegetative reactions, hydrotherapy, moxibustion or acupressure have been found to be empirically suitable. Motoric stress reactions (e.g. muscle tension) are improved preferably through relaxation techniques, such as muscle relaxation according to Jacobson or simple respiratory relaxation as an attentiveness exercise [16]. Emotional-cognitive stress reactions such as depressive or aggressive disgruntlement require a rational approach, such as the general scrutinizing of one’s own way of thinking and conducting (e.g. “must I always be well liked?” – “must I always be perfect?”).

The YangSheng contribution to the stress management package consists of practicing QiGong exercises. Emphasis is placed especially on a special form of QiGong, the so called “Six Healing Sounds”. They are related to six “organs” and accordingly allocated to the determined constitutional types [13]. From TCM perspective, the “organs” have complex biological-psychological-energetic functions, which may deviate from the western anatomy or physiology of organs. Conspicuous features in individual basis-functions and basis-competences can be reduced with the help of counselling recipes (“info@zepte”) and practical exercises in the form of detailed programs with defined target values (e.g. resistance, sleep), or, for those tested and found to be healthy, be trained for health maintenance in the sense of health support. For example, TCM thermal application to certain acupuncture points (moxibustion) can, within the scope of intensive dietary measures, ease the feeling of faintness with a feeling of coldness and shivering. Further YangSheng elements are “Tuina-massage-self-help” and “therapeutic tea preparation”. Some procedures require special multimedia processing (photos, audio etc.).

Study design

Pilot-study with a pre-post observational design and at least 12 people meeting the inclusion criteria had to be recruited. Six (6) months and three sequential examinations (at months 0, 3 and 6) were designed.

Recruitment and participants

Measures for recruitment of feasible study participants consisted of search in the databases of involved general practices (GP), conduction of local action days to attract population interested in stress reduction, and advertisements in local media between September and October, 2015. All interested persons were informed about basic information around the study and screened for the main inclusion criteria. All persons who apparently complied with the requirements of the study were invited to a personal appointment with the trial physician to undergo a comprehensive examination of the criteria for inclusion and exclusion. Potential participants were informed on background, objectives, benefit and risks of the study by a leaflet, as well as orally by the trial physician.

Inclusion / exclusion criteria

Participants of both sexes, aged 18 to 67 years, with moderate stress, measured by Tedium Questionnaire (score 3.2 – 4.5) [17] were included to the study. A written informed consent was mandatory. Persons were not included, if one of the following exclusion criteria was present: not legally competent, insufficient skills in German language, no private access to internet, already known pregnancy, known psychiatric disease, including depression (5-WellBeing Index [18]). Beyond that, a severe symptom load in at least one of the subscales of ICD-10-Symptom-Rating ISR [19]: depressive syndrome, anxiety disorder, compulsive-obsessive syndrome, somatoform disorder, eating disorder resp. a high overall score of ISR led to exclusion. Further exclusion criteria were: hypertension grade > I (systolic BP ≥ 160 mmHg or diastolic BP ≥ 100 mmHg) with/without hypertensive medication, hyperthyroidism, known heart disease, known gastric or duodenal ulcers, disease-related impairments hampering certain elements of the lifestyle program or therapeutic conditions not compatible with lifestyle modifications.

Outcome measures

The primary outcome measures to evaluate the benefit of the intervention were changes in Burnout Questionnaire (Tedium scale) and ICD-Symptom-Rating (ISR) (as well as reduction of the total score of Perceived Stress Questionnaire PSQ [20], after six months).

Secondary outcomes were changes in Life Satisfaction Questionnaire (FLZ, [21]), psycho-vegetative indicators, body-mass-index, waist circumference, blood pressure and heart frequency. The occurrence of adverse events was captured systematically at each physical examination following the baseline test. All outcomes were self-reported within the web-based health-portal. During the screening phase, additionally a 5-WHO-Wellbeing-index Questionnaire for rating of depression and vitality was used.

Descriptive analysis

All captured data were analyzed descriptively by appropriate statistical parameters: absolute and relative frequencies for

categorical data and arithmetic means, medians, standard deviations for numerical data. In accordance with the given pilot study, no statistical tests were performed. IBM SPSS Statistics (version 22) was used for all statistical analyses.

RESULTS

26 persons (20 female) were recruited to be screened for inclusion and exclusion criteria. Mean age was 44.4 (sd=9.4) years. 14 persons did not fulfil the predefined criteria resulting in a study group of 12 individuals (10 female, 2 male, mean age=42.8 with range from 27 to 56 years). In some cases, the clinical impression by the involved trial physicians was also used for the final decision of inclusion to the intervention.

All 12 individuals followed and fulfilled the training-plan, but 2 participants did not complete documentation within their personal health portal at month 6. The course of all indicators for stress and mental health showed remarkable ameliorations (Table 1).

The mean total score of the Perceived Stress questionnaire (PSQ) was reduced from 51.53 (sd=14.62) at month 0 to 27.17 (sd=16.35) at month 6. Improvement of the total score was mainly due to the decrease of the subscore "tension". Subscore "joy" was slightly elevated. Applying empirically based threshold values to categorize the level of perceived stress as "normal", "slightly elevated" or "strikingly elevated" lead to the results presented in Figure 2. During the lifestyle intervention, the percentage of subjects with "strikingly elevated" scores declined from 42% to zero while the rate of "normal" levels climbed from 33 to 80%.

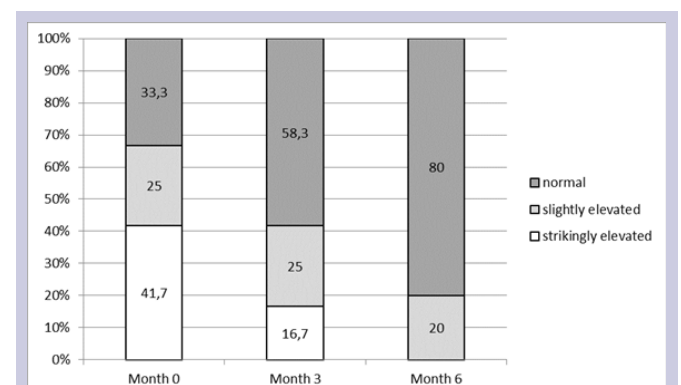


Figure 2: Relative frequencies of categories for the level of perceived stress (PSQ total score) before and during lifestyle program SEPP; n=12 participants (month 0: n=12)

Similarly, the mean scores of the Burnout questionnaire decreased from 3.95 (sd=0.44) to 2.73 (sd=0.91) at the end of the intervention program. The leading subscore was "exhaustion" which showed the most pronounced change.

Additionally, participants experienced a marked lowering of mental symptom load. Mean scores for anxiety and depressive syndrome, as well as the total score of ISR showed clinically relevant decreases (Table 1). The same was for an increase of well-being and vitality scores captured by WHO-5-well-being questionnaire.

Table 1: Longitudinal results in indicators of stress, psychopathological syndromes, well-being, life satisfaction and vegetative stability;

	Month 0 N=12		Month 3 N=12		Month 6 N=10	
	m	sd	M	sd	m	sd
Burnout Tediumscale						
Total score	3.95	0.44	2.97	0.84	2.73	0.91
- Demoralization	3.55	0.53	2.83	0.91	2.48	0.92
- Exhaustion	4.51	0.39	3.28	1	3.13	1.05
- Loss of motive	4.08	0.58	2.87	0.73	2.76	0.95
Perceived Stress Questionnaire						
Total score	51.53	14.62	35.83	20.44	27.17	16.35
- Demands	62.78	18.74	44.44	20.17	35.33	15.73
- Tension	61.11	22.71	33.89	24.03	25.33	21.27
- Joy	50.56	20.59	57.78	25	68	23.89
- Worries	32.78	16.69	22.78	18.96	16	18.65
ICD Symptom Rating ISR						
Total score	1.3	0.34	0.71	0.39	0.58	0.42
- Anxiety syndrome	1.94	0.84	1.13	0.68	1.05	0.83
- Depressive syndrome	1.56	0.39	0.63	0.55	0.65	0.57
- Eating disorder	1	0.91	0.81	0.73	0.6	0.68
- Somatoform disorder	1.08	0.61	0.42	0.65	0.23	0.52
- Compulsive-obsessive disorder	1.75	0.7	1.14	0.81	0.9	0.69
WHO-5 Well-being						
- Well-being	8.5	3.9	16.58	5.35	17.2	4.08
- Vitality	39.17	9.73	67.92	18.76	66	19.55
Questions on Life satisfaction						
Total score	36.08	26.77	66.08	35.13	67.4	43.22
- Friends/acquaintances	3.58	4.4	4.08	4.94	6.5	7.93
- Leisure time/hobbies	1.33	3.5	4.83	5.02	4.9	6.44
- Health	0.25	4.96	5.17	9.67	9.6	8.32
- Income/financial security	8	6.52	9.42	8.78	10.5	6.92
- Occupation/work	3.33	4.94	9.25	7.25	7.8	4.89
- Housing/living conditions	9.17	7.22	13.17	6.18	10.2	5.98
- Family life/children	7.33	7.08	13.5	6.75	12	6.43
- Partner relationship/sexuality	3.08	7.22	6.67	8.96	5.9	8.24
Vegetative stability						
Total score	42.25	14.9	28.67	13.87	26.9	13.54
- Sleep	5	3.13	2.75	2.01	2.7	1.64
- Orthostatic adaptability	1.5	1.62	0.92	1.16	1.3	1.16
- Thermoregulation	4.5	2.78	3.67	2.9	4.3	2.21

Abbreviations and Legend: m=arithmetic mean, sd=standard deviation; Tedium scale (17); Perceived Stress Questionnaire (20); ICD-10 Symptom Rating (19); WHO-5 Wellbeing (18); Question of Life Satisfaction (21).

The mean total score for life satisfaction increased from 36.1 (sd=26.8) at month 0 to 67.4 (sd=43.2) at the end of the observation period. Vegetative stability increased, which was expressed in lowering of the total score of the vegetative symptoms questionnaire.

Metabolic parameters like body weight, BMI, circumference, and risk for pre-diabetes experienced no change during the intervention. In contrast, data of both blood pressure values (syst./dia.) decreased from 132/84 (sd=17/8) mmHg at month 0 to 121/75 (sd=9/6) mmHg at month 6.

Preliminary data of TCM constitutional types from participants with stress-induced exhaustion indicate that at month zero the two most prominent types were "Yang deficiency" in 42% and "Qi depression" in 25% of the participants with minor changes at month three. Due to attrition of the sample, findings from month six are less meaningful.

DISCUSSION

The development of SEPP interconnects both Western and far eastern health care and sickness prevention in a modern and appealing manner. The implementation of SEPP in a BAVARIA spa region may help persons strengthen self-perception and self-reflection of maladaptive behavior and of inadequate emotional-cognitive assessments and give support in self-help techniques from western lifestyle medicine and Traditional Chinese Medicine to overcome these problems. Further, the harmonization of functions of the independent neuro-vegetative nervous system through different stimulating techniques and self-help competences is an important ratio of the lifestyle concept. Modern web technologies assist adherence and implement behavioral changes in everyday life by serving with modern performance measurement systems and self-report. They enable user to obtain feedback, by monitoring and evaluation of behavioral change and attitudes. But sustained personal contact with coaches is needed to make participants successful in daily routines of life.

So far it sounds theoretical, based on concept and literature. Implementation of such comprehensive concepts in routine care is quite a different issue and requires a difficult interplay with different statutory sickness funds, physicians, coaches and participants themselves. Convincing data for all the partners involved can only be induced by rigorous controlled clinical trials. Nevertheless, to start exploring feasibility, to calculate sample size for a future randomized controlled trial and to find out more about acceptance and effectiveness, it was reasonable to perform a pilot-study, as done here.

In this small pilot study, 26 people with stress-based exhaustion were screened by a web-based tool as part of the VITERIO® health portal. A portfolio of screening indicators for mental disorders was explored to find out a suitable group of participants between 12 until 15 people for pilot. Tedium measure and ISR turned out to be appropriate questionnaires for the identification of people with severe stress-related symptoms, but without manifestation of psychosomatic disorders like depression. In this context, 5-WHO-Wellbeing Index Questionnaire was proved to be too sensitive

for exclusion. Finally, 10 women and 2 men were selected and available for the pilot study group. Exhaustion, as an important symptom of the group, was adequately characterized by sub-dimensions like fatigue, loss of motivation in Tedium measure, low vitality in 5-WHO Wellbeing Index and sleep disturbances in neuro-vegetative questionnaire. All indicators for stress-based disorders showed relevant improvements in a consistent way. These promising results were already realized at month 3 and mostly held until month 6. The course of life satisfaction indicates a gain of confidence in body health and other lifestyle areas like work and family, which confirmed the effectiveness of the program. Finally, it is worthwhile to mention that increased values of blood pressure normalized during the intervention.

Nevertheless, it remains still unclear, what proportional value diagnostic efforts have when constitutional types are determined. Is there any additional benefit when giving different advices in nutrition and exercise following features of these constitutions?

CONCLUSION

SEPP is a feasible concept for a web-based lifestyle program in a specialized SPA-region with suspected effectiveness in people with perceived stress and should be evaluated in a randomized controlled design next. The general relevance of the project lies especially in the development of a better medical quality and image building, in web-based medical services, and in the economic efficiency of health resort medical care in Bad Kötzing.

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DISCLOSURE

The authors declare no conflicts of interest.

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